

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER

004974.01103

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/568,762

INTERNATIONAL APPLICATION NO.  
PCT/EP2004/009199

INTERNATIONAL FILING DATE  
17 August 2004

PRIORITY DATE CLAIMED  
30 August 2003

TITLE OF INVENTION

**DIAGNOSTICS AND THERAPEUTICS FOR DISEASES ASSOCIATED WITH KALLIKREIN 8 (KLK8)**

APPLICANT(S) FOR DO/EO/US

**GOLZ, Stefan et al**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☐ Express Mail Label No.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO (if known, see 37 CFR 1.5) <b>10/568,762</b>		INTERNATIONAL APPLICATION NO. <b>PCT/EP2004/009199</b>		ATTORNEY'S DOCKET NUMBER <b>004974.01103</b>	
23. Other items or information: Response to Notification of Missing Requirements Under 35 U.S.C. § 371 Copy of Notification of Missing Requirements USPTO Form 1449 with 5 copies of references Postcard					
The following fees have been submitted:				CALCULATIONS PTO USE	
24. <input type="checkbox"/> Basic national fee . . . . . \$300				\$	\$0.00
25. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article \$0 All other situations. . . . . \$200				\$	\$0.00
26. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). . . \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. . . . . \$100 International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. . . . . \$400 All other situations. . . . . \$500				\$	\$0.00
<b>TOTAL OF 24, 25 and 26 =</b>				\$	\$0.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE		
- 100 =	0 /50 =	0	x \$250.00	\$	\$0.00
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	\$130.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =	0	x \$50.00	\$	\$0.00
Independent claims	- 3 =	0	x \$200.00	\$	\$0.00
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00				\$	\$0.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	\$130.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				\$	\$0.00
<b>SUBTOTAL =</b>				\$	\$130.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	\$0.00
<b>TOTAL NATIONAL FEE =</b>				\$	\$130.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +				\$	\$40.00
<b>TOTAL FEES ENCLOSED =</b>				\$	\$170.00
				Amount to be	\$
				Amount to be	\$

 08/15/2006 LLANDGRA 00000057 190733 10568762  
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 19-0733 in the amount of \$ \$170.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0733. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

BANNER & WITCOFF, LTD.

Customer Number: 22907

  
SIGNATURE

Lisa M. Hemmendinger  
NAME

42,653  
REGISTRATION NUMBER

August 10, 2006  
DATE

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	:	
Stefan GOLZ et al	:	
Int'l Application No.: PCT/EP2004/009199	:	
Serial No. 10/568,762	:	Art Unit: To Be Assigned
Filed: February 21, 2006	:	Examiner: To Be Assigned
For: <i>DIAGNOSTICS AND</i>	:	Atty Docket: 004974.01103
<i>THERAPEUTICS FOR DISEASES</i>	:	
<i>ASSOCIATED WITH KALLIKREIN 8</i>	:	
<i>(KLK8)</i>	:	

**RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C.**  
**§ 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

Commissioner of Patents  
U.S. Patent and Trademark Office  
Customer Service Window  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

Applicants submit the following documents to complete the requirements for acceptance under 35 U.S.C. § 371:

1. Fee Transmittal Sheet Form PTO-1390 (Modified) in Duplicate;
2. Copy of the Notification of Missing Requirements mailed June 12, 2006 and

Serial No. 10/568,762

Response to Missing Requirements  
Under 35 U.S.C. 371 In The United States  
Designated/Elected Office (DO/EO/US)

3. Executed Declaration for Patent Application
4. Executed Assignment with Recordation cover sheet.
5. IDS/1449 with copies of 5 references
6. Copy of International Search Report

Please charge our Deposit Account No. 19-0733 in the amount of \$170.00, as follows:


\$ 130.00 Late declaration surcharge

\$ 40.00 Recordation of Assignment.

We believe no additional fees are required. If this is incorrect, please charge our Deposit Account No. 19-0733.

Respectfully submitted,

BANNER & WITCOFF, LTD.

By:   
Lisa M. Hemmendinger  
Registration No. 42,653

Date: August 10, 2006

Banner & Witcoff, Ltd.  
Customer Number: 22907

LMH/mhn



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/568,762	Stefan Golz	0049701103

22907  
BANNER & WITCOFF  
1001 G STREET N W  
SUITE 1100  
WASHINGTON, DC 20001

**RECEIVED**

JUN 16 2006

BANNER &amp; WITCOFF, LTD.

INTERNATIONAL APPLICATION NO.	
PCT/EP04/09199	
I.A. FILING DATE	PRIORITY DATE
08/17/2004	08/30/2003

CONFIRMATION NO. 4836

371 FORMALITIES LETTER



\*OC000000019229327\*

Date Mailed: 06/13/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 02/21/2006
- Copy of the International Search Report filed on 02/21/2006
- Preliminary Amendments filed on 02/21/2006
- Information Disclosure Statements filed on 02/21/2006
- Biochemical Sequence Diskette filed on 02/21/2006
- Request for Immediate Examination filed on 02/21/2006
- U.S. Basic National Fees filed on 02/21/2006
- Priority Documents filed on 02/21/2006
- Specification filed on 02/21/2006
- Claims filed on 02/21/2006
- Abstracts filed on 02/21/2006
- Drawings filed on 02/21/2006

Docketed 01/16/06  
 Attny OHIT/CMH  
 Case Ref 004974-01103  
 Action Resp. Notif. Miss. Requirements  
 Due Date 8/13/06  
 Last Day 1/13/07  
 By AR

*mul*  
6/19

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

## SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Surcharge.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

LAMONT M HUNTER

Telephone: (703) 308-9140 EXT 201

## PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/568,762	PCT/EP04/09199	0049701103